K123953

MAY 2 2013

510(k) SUMMARY

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Hkatz@AlfaWassermannUS.com Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237	
Date Summary Prepared:	April 25, 2013	
Device:	Trade Name:	ACE Carbon Dioxide (CO_2-LC) Reagent
	Classification:	Class 2
	Common/Classification Name:	Enzymatic, Carbon-Dioxide (21 C. F.R. § 862.1160) Product Code KHS
	Trade Name:	ACE Direct Bilirubin Reagent
	Classification:	Class 2
	Common/Classification Name:	Diazo Colorimetry, Bilirubin (21 C. F.R. § 862.1110) Product Code CIG
	Trade Name:	ACE Total Bilirubin Reagent
	Classification:	Class 2
	Common/Classification Name:	Diazo Colorimetry, Bilirubin (21 C. F.R. § 862.1110) Product Code CIG
	Trade Name:	ACE Magnesium Reagent
	Classification:	Class 1, reserved
	Common/Classification Name:	Photometric Method, Magnesium (21 C. F.R. § 862.1495) Product Code JGJ

Predicate Devices:	Alfa Wassermann ACE Carbon Dioxide (CO2-LC) Reagent, ACE Direct Bilirubin Reagent, ACE Total Bilirubin Reagent, and ACE Magnesium Reagent (k931786)
Device Descriptions:	In the ACE Carbon Dioxide (CO_2-LC) Reagent assay, serum carbon dioxide (in the form of bicarbonate) reacts with phosphoenolpyruvate in the presence of phosphoenolpyruvate carboxylase and magnesium to yield oxaloacetic acid and phosphate. In the presence of malate dehydrogenase, the reduced cofactor is oxidized by oxaloacetic acid. The reduced cofactor absorbs strongly at 408 nm whereas its oxidized form does not. The rate of decrease in absorbance, monitored bichromatically at 408 nm/692 nm, is proportional to the carbon dioxide content of the sample. In the ACE Direct Bilirubin Reagent assay, sodium nitrite added to sulfanilic acid forms diazotized sulfanilic acid. Bilirubin glucuronide in serum reacts with diazotized sulfanilic acid to form azobilirubin, which absorbs strongly at 554 nm. The increase in absorbance, measured bichromatically at 554 nm/692 nm, one minute after sample addition, is directly proportional to the direct bilirubin concentration. In the ACE Total Bilirubin Reagent assay, sodium nitrite, when added to sulfanilic acid, forms diazotized sulfanilic acid. Bilirubin in serum reacts with diazotized sulfanilic acid to form azobilirubin, which absorbs strongly at 554 nm. The inclusion of dimethyl sulfoxide (DMSO) in the reagent as an accelerator causes both direct and indirect bilirubin to react rapidly. The increase in absorbance, measured bichromatically at 554 nm/692 nm, is directly proportional to the total bilirubin concentration in the sample. Magnesium ions in serum react with Xylidyl blue-1 in an alkaline medium to produce a red complex which is measured bichromatically at 525 nm/692 nm. The intensity of color produced is directly proportional to the magnesium concentration in the sample. EGTA prevents calcium interference by preferential chelation of calcium present in the sample. A surfactant system is included to remove protein interference.

Intended Use:	Indications for Use:
	The ACE Carbon Dioxide (CO2-LC) Reagent is intended for the quantitative determination of carbon dioxide concentration **in serum and lithium heparin plasma** using the ACE, ACE *Alera*®, and ACE Axcel Clinical Chemistry Systems. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance. This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only. The ACE Direct Bilirubin Reagent is intended for the quantitative determination of direct bilirubin concentration **in serum and lithium heparin plasma** using the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems. Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic, hematological and metabolic disorders, including hepatitis and gall bladder block. This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only The ACE Total Bilirubin Reagent is intended for the quantitative determination of total bilirubin concentration in **serum and lithium heparin plasma** using the ACE, ACE Alera and ACE Axcel Clinical Chemistry System. Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells is used in the diagnosis and treatment of liver, hemolytic, hematological and metabolic disorders, including hepatitis and gall bladder block. This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only. The ACE Magnesium Reagent is intended for the quantitative determination of magnesium in **serum and lithium heparin plasma** using the ACE, ACE Alera and ACE Axcel Clinical Chemistry Systems. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium). This test is intended for use in clinical laboratories and physician office laboratories. For *in vitro* diagnostic use only.

Technological Characteristics:	The ACE Carbon Dioxide (CO_2-LC) Reagent consists of a single reagent bottle. The reagent contains Phosphoenolpyruvate, nicotinamide adenine dinucleotide, analog, reduced, phosphoenol pyruvate carboxylase and malate dehydrogenase. The ACE Direct Bilirubin Reagent is composed of two reagent bottles (Direct Bilirubin Reagent and Sodium Nitrite Reagent). The reagents contain Sulfanilic Acid, hydrochloric acid, and sodium nitrite. The ACE Total Bilirubin Reagent is composed of two reagent bottles (Total Bilirubin Reagent and Sodium Nitrite Reagent). The reagents contain sulfanilic acid, hydrochloric Acid, DMSO and sodium Nitrite. The ACE Magnesium Reagent is composed of a single reagent bottle. The reagent contains Xylidyl blue-1 and EGTA.

Device Comparison with Predicate

Comparison of similarities and differences with predicate device

ACE Carbon Dioxide (CO_2-LC) Reagent

CO_2-LC	Candidate Device	Predicate Device K931786 (ACE CO_2-LC)
Intended Use	The ACE Carbon Dioxide (CO2-LC) Reagent is intended for the quantitative determination of carbon dioxide concentration.	Same
Platforms	ACE, ACE *Alera*®, and ACE Axcel Clinical Chemistry Systems	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	7 days	Same
On-Board Stability	14 days	Same
Sample Type	Serum and lithium heparin plasma	Serum
Sample Volume	6 µL	Same
Reaction Volume	156 µL	Same
Expected Values	23 - 29 mEq/L	Same
Measuring Range	4 - 50 mEq/L	Same
Sample Stability	Separated from cells, carbon dioxide is stable for 7 days at 4-8°C and for 2 weeks at -20 °C.	Same

Device Comparison with Predicate

ACE Direct Bilirubin Reagent

Direct Bilirubin	Candidate Device	Predicate Device K931786 (ACE Direct Bilirubin)
Intended Use/ Indications for Use	The ACE Direct Bilirubin Reagent is intended for the quantitative determination of direct bilirubin concentration.	Same
Platforms	ACE, ACE *Alera*®, and ACE Axcel Clinical Chemistry Systems	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	30 days	Same
On-Board Stability	30 days	Same
Sample Type	Serum and lithium heparin plasma	Serum
Sample Volume	20 µL	Same
Reaction Volume	355 µL	Same
Expected Values	<0.2 mg/dL	Same
Measuring Range	0.1 - 14.0 mg/dL	Same
Sample Stability	Samples must be stored away from sunlight or fluorescent lights because bilirubin is subject to photodegradation. Specimens may be stored at 4-8°C for 7 months or 6 months at -20°C.	Same

ACE Total Bilirubin Reagent

Total Bilirubin	Candidate Device	Predicate Device K931786 (ACE Total Bilirubin)
Intended Use/ Indications for Use	The ACE Total Bilirubin Reagent is intended for the quantitative determination of total bilirubin concentration.	Same
Platforms	ACE, ACE *Alera*®, and ACE Axcel Clinical Chemistry Systems	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	30 Days	Same
On-Board Stability	30 Days	Same
Sample Type	Serum and lithium heparin plasma	Serum
Sample Volume	20 µL	Same
Reaction Volume	380 µL	Same
Expected Values	0.3 - 1.2 mg/dL	Same
Measuring Range	0.2 - 40.0 mg/dL	
Sample Stability	Samples must be stored away from sunlight or fluorescent lights because bilirubin is subject to photodegradation. Serum samples must be analyzed within 7 days at 4-8 °C. Frozen samples are stable for 6 months at -20°C.	Same

Device Comparison with Predicate

ACE Magnesium Reagent

Magnesium	Candidate Device	Predicate Device K931786 (ACE Magnesium)
Intended Use/ Indications for Use	ACE Magnesium Reagent is intended for the quantitative determination of magnesium.	Same
Platforms	ACE, ACE *Alera*®, and ACE Axcel Clinical Chemistry Systems	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	30 Day	Same
On-Board Stability	30 Days	Same
Sample Type	Serum and lithium heparin plasma	Serum
Sample Volume	3 µL	Same
Reaction Volume	488 µL	Same
Expected Values	1.6 - 2.6 mg/dL	Same
Measuring Range	0.4 - 6.1 mg/dL	
Sample Stability	Serum magnesium is stable for 7 days at 4-8°C and 1 year at -20 °C if the serum is separated from the erythrocytes.	Same

Performance Data:

In-House Precision - Serum vs. Plasma

Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE, ACE *Alera* and ACE Axcel Clinical Chemistry Systems

In-House Precision: Serum vs. Plasma – ACE CO2-LC Reagent

	Precision (SD, %CV)								
CO2-LC mEq/L	**ACE Mean**	**Within-Run**	**Total**	**Alera Mean**	**Within-Run**	**Total**	**Axcel Mean**	**Within-Run**	**Total**
Serum Low	24.0	0.27, 1.1%	1.34, 5.6%	24.6	0.61, 2.5%	1.85, 7.5%	23.9	0.48, 2.0%	1.56, 6.5%
Serum Mid	34.1	0.72, 1.2%	1.22, 3.6%	35.7	0.41, 1.2%	1.17, 3.3%	34.3	0.52, 1.5%	1.26, 3.7%
Serum High	45.6	0.57, 2.8%	2.7, 3.2%	47.0	0.55, 1.2%	2.7, 3.2%	45.4	0.25, 0.6%	1.19, 2.6%
Plasma Low	22.9	0.29, 1.3%	0.86, 3.8%	23.3	0.71, 3.0%	1.43, 6.1%	23.1	0.29, 1.3%	0.86, 3.8%
Plasma Mid	33.7	0.41, 1.2%	1.85, 5.5%	34.8	0.34, 1.0%	1.77, 5.1%	33.8	0.24, 0.7%	1.69, 5.0%
Plasma High	45.6	0.46, 1.0%	1.14, 2.5%	46.9	0.46, 1.0%	1.10, 2.4%	45.3	0.47, 1.0%	1.05, 2.3%

In-House Precision: Serum vs. Plasma – ACE Direct Bilirubin Reagent

	Precision (SD, %CV)								
Direct Bilirubin mg/dL	**ACE Mean**	**Within-Run**	**Total**	**Alera Mean**	**Within-Run**	**Total**	**Axcel Mean**	**Within-Run**	**Total**
Serum Low	0.2	0.04, 24.5%	0.05, 30.0%	0.2	0.03, 16.0%	0.04, 20.1%	0.1	0.02, 12.5%	0.02, 14.0%
Serum Mid	4.7	0.04, 0.9%	0.06, 1.2%	4.7	0.06, 1.4%	0.10, 2.2%	4.7	0.08, 1.6%	0.08, 1.6%
Serum High	8.4	0.05, 0.6%	0.09, 1.1%	8.3	0.06, 0.8%	0.09, 1.1%	8.3	0.13, 1.5%	0.14, 1.7%
Plasma Low	0.1	0.03, 26.6%	0.03, 26.6%	0.1	0.03, 23.4%	0.05, 35.4%	0.1	0.02, 16.6	0.02, 19.7%
Plasma Mid	4.8	0.04, 0.8%	0.05, 1.1%	4.8	0.08, 1.7%	0.13, 2.8%	4.8	0.11, 2.4%	0.11, 2.4%
Plasma High	8.5	0.09, 1.1%	0.14, 1.6%	8.5	0.06, 0.7%	0.10, 1.1%	8.5	0.16, 1.9%	0.20, 2.3%

Performance Data:

In-House Precision – Serum vs. Plasma

In-House Precision: Serum vs. Plasma – ACE Total Bilirubin Reagent

	Precision (SD, %CV)								
Total Bilirubin mg/dL	**ACE Mean**	**Within-Run**	**Total**	**Alera Mean**	**Within-Run**	**Total**	**Axcel Mean**	**Within-Run**	**Total**
Serum Low	0.3	0.07, 21.3%	0.07, 21.3%	0.3	0.04, 11.0%	0.05, 15.7%	0.3	0.04, 13.4%	0.04, 13.9%
Serum Mid	13.3	0.13, 1.0%	0.13, 1.0%	13.0	0.14, 1.1%	0.14, 1.1%	13.3	0.13, 1.0%	0.13, 1.0%
Serum High	26.1	0.18, 0.7%	0.21, 0.8%	25.5	0.12, 0.5%	0.12, 0.5%	26.1	0.11, 0.4%	0.17, 0.7%
Plasma Low	0.2	0.04, 20.3%	0.05, 21.3%	0.2	0.06, 23.7%	0.07, 29.4%	0.2	0.04, 20.6%	0.05, 23.9%
Plasma Mid	13.2	0.11, 0.8%	0.12, 0.9%	13.0	0.13, 1.0%	0.14, 1.1%	13.2	0.06, 0.5%	0.07, 0.5%
Plasma High	26.2	0.15, 0.6%	0.17, 0.6%	25.6	0.12, 0.5%	0.18, 0.7%	26.1	0.13, 0.5%	0.14, 0.5%

In-House Precision: Serum vs. Plasma – ACE Magnesium Reagent

	Precision (SD, %CV)								
Magnesium mg/dL	**ACE Mean**	**Within-Run**	**Total**	**Alera Mean**	**Within-Run**	**Total**	**Axcel Mean**	**Within-Run**	**Total**
Serum Low	2.0	0.10, 5.1%	0.12, 5.9%	2.1	0.06, 3.1%	0.09, 4.3%	1.9	0.07, 3.6%	0.08, 4.3%
Serum Mid	3.7	0.09, 2.5%	0.11, 3.0%	3.8	0.06, 1.7%	0.07, 1.8%	3.7	0.09, 2.6%	0.09, 2.6%
Serum High	5.6	0.05, 1.0%	0.10, 1.7%	5.6	0.08, 1.4%	0.09, 1.6%	5.5	0.08, 1.4%	0.09, 1.7%
Plasma Low	1.7	0.08, 4.7%	0.11, 6.2%	1.7	0.06, 3.5%	0.07, 4.1%	1.7	0.04, 2.4%	0.11, 6.8%
Plasma Mid	3.5	0.09, 2.7%	0.10, 2.8%	3.5	0.09, 2.4%	0.09, 2.6%	3.4	0.09, 2.8%	0.13, 3.7%
Plasma High	5.3	0.04, 0.9%	0.10, 1.9%	5.4	0.09, 1.6%	0.10, 1.8%	5.3	0.05, 1.0%	0.09, 1.8%

Performance Data:

In-House Matrix Comparison – Serum vs. Plasma

Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE, ACE *Alera* and ACE Axcel Clinical Chemistry Systems

In-House Matrix Comparison: Serum vs. Plasma – ACE CO2-LC Reagent

System	Range	Results - Serum vs. Plasma
ACE 53 pairs	4.9-47.9 mEq/L	Slope: 1.031 Intercept: -1.03 Correlation: 0.9922 Std. Error Est: 1.13 Confidence Interval Slope: 0.995 to 1.067 Confidence Interval Intercept: -2.11 to 0.04
ACE Alera 54 pairs	4.7-48.2 mEq/L	Slope: 1.000 Intercept: -0.09 Correlation: 0.9955 Std. Error Est: 0.86 Confidence Interval Slope: 0.974 to 1.027 Confidence Interval Intercept: -0.81 to 0.64
ACE Axcel 51 pairs	5.5-47.9 mEq/L	Slope: 0.988 Intercept: -0.35 Correlation: 0.9889 Std. Error Est: 1.12 Confidence Interval Slope: 0.946 to 1.031 Confidence Interval Intercept: -1.29 to 0.60

In-House Matrix Comparison: Serum vs. Plasma – ACE Direct Bilirubin Reagent

System	Range	Results - Serum vs. Plasma
ACE 102 pairs	0.1-10.8 mg/dL	Slope: 1.021 Intercept: 0.00 Correlation: 0.9982 Std. Error Est: 0.10 Confidence Interval Slope: 1.009 to 1.033 Confidence Interval Intercept: -0.02 to 0.03
ACE Alera 101 pairs	0.1-11.0 mg/dL	Slope: 1.005 Intercept: 0.01 Correlation: 0.9978 Std. Error Est: 0.11 Confidence Interval Slope: 0.992 to 1.018 Confidence Interval Intercept: -0.02 to 0.03
ACE Axcel 56 pairs	0.1-13.1 mg/dL	Slope: 1.004 Intercept: 0.00 Correlation: 0.9983 Std. Error Est: 0.16 Confidence Interval Slope: 0.988 to 1.020 Confidence Interval Intercept: -0.04 to 0.05

Performance Data:

In-House Matrix Comparison – Serum vs. Plasma

In-House Matrix Comparison: Serum vs. Plasma – ACE Total Bilirubin Reagent

System	Range	Results - Serum vs. Plasma
ACE 102 pairs	0.1-37.2 mg/dL	Slope: 1.017 Intercept: 0.01 Correlation: 0.9996 Std. Error Est: 0.15 Confidence Interval Slope: 1.011 to 1.022 Confidence Interval Intercept: -0.03 to 0.04
ACE Alera 102 pairs	0.2-36.7 mg/dL	Slope: 1.020 Intercept: 0.00 Correlation: 0.9993 Std. Error Est: 0.20 Confidence Interval Slope: 1.012 to 1.028 Confidence Interval Intercept: -0.05 to 0.04
ACE Axcel 56 pairs	0.2-35.5 mg/dL	Slope: 1.008 Intercept: 0.00 Correlation: 0.9995 Std. Error Est: 0.22 Confidence Interval Slope: 1.000 to 1.017 Confidence Interval Intercept: -0.06 to 0.07

In-House Matrix Comparison: Serum vs. Plasma – ACE Magnesium Reagent

System	Range	Results - Serum vs. Plasma
ACE 101 pairs	1.2-5.8 mg/dL	Slope: 0.948 Intercept: 0.08 Correlation: 0.9703 Std. Error Est: 0.19 Confidence Interval Slope: 0.902 to 0.994 Confidence Interval Intercept: -0.02 to 0.18
ACE Alera 101 pairs	1.0-5.9 mg/dL	Slope: 0.986 Intercept: 0.05 Correlation: 0.9817 Std. Error Est: 0.15 Confidence Interval Slope: 0.948 to 1.024 Confidence Interval Intercept: -0.06 to 0.10
ACE Axcel 55 pairs	1.2-5.8 mg/dL	Slope: 0.986 Intercept: 0.025 Correlation: 0.9892 Std. Error Est: 0.125 Confidence Interval Slope: 0.947 to 1.026 Confidence Interval Intercept: -0.61 to 0.111

Performance Data:

Precision - POL

POL – Precision studies at 3 POC sites for ACE *Alera* Clinical Chemistry Systems

(ACE system was also tested concurrently and comparable precision was obtained)

CO2_LC			ACE Result mEq/L SD, %CV		Mean	ACE Alera Result mEq/L SD, %CV	
Lab	**Sample**	**Mean**	**Within-Run**	**Total**		**Within-Run**	**Total**
In-House	1	21.2	0.33 SD	0.63 SD	21.1	0.43 SD	0.81 SD
			1.60%	3.00%		2.00%	3.90%
POL 1	1	20.3	0.68 SD	0.88 SD	22.3	0.28 SD	0.67 SD
			3.30%	4.30%		1.30%	3.00%
POL 2	1	23	0.55 SD	1.54 SD	22.4	0.59 SD	0.84 SD
			2.40%	6.70%		2.60%	3.80%
POL 3	1	22.3	0.42 SD	1.10 SD	24.3	0.37 SD	1.53 SD
			1.90%	4.90%		1.50%	6.30%
In-House	2	24.2	0.46 SD	0.66 SD	24.2	0.42 SD	0.77 SD
			1.90%	2.70%		1.70%	3.20%
POL 1	2	24.9	0.77 SD	1.38 SD	25.6	0.32 SD	0.63 SD
			3.10%	5.60%		1.30%	2.40%
POL 2	2	26.2	0.43 SD	1.92 SD	26	0.24 SD	1.00 SD
			1.70%	7.40%		0.90%	3.90%
POL 3	2	25.9	0.34 SD	1.08 SD	27.8	0.29 SD	1.60 SD
			1.30%	4.20%		1.10%	5.80%
In-House	3	27.3	0.49 SD	0.65 SD	27	0.43 SD	0.83 SD
			1.80%	2.40%		1.60%	3.10%
POL 1	3	30.4	0.73 SD	1.75 SD	28.4	0.39 SD	0.94 SD
			2.40%	5.80%		1.40%	3.30%
POL 2	3	29.6	0.62 SD	1.88 SD	29.3	0.48 SD	0.94 SD
			2.10%	6.40%		1.60%	3.20%
POL 3	3	29.5	0.26 SD	1.08 SD	30.7	0.29 SD	1.60 SD
			0.90%	3.60%		1.00%	5.20%

Performance Data at POL:

Precision - POL

DBILI			ACE Result mg/dL SD, %CV			ACE Alera Result mg/dL SD, %CV	
Lab	**Sample**	**Mean**	**Within-Run**	**Total**	**Mean**	**Within-Run**	**Total**
In-House	1	1.0	0.03 SD	0.03 SD	1.0	0.05 SD	0.05 SD
			2.90%	2.90%		5.10%	5.40%
POL 1	1	0.9	0.04 SD	0.05 SD	0.9	0.04 SD	0.05 SD
			4.20%	4.90%		4.80%	5.40%
POL 2	1	0.9	0.03 SD	0.05 SD	0.9	0.02 SD	0.02 SD
			3.30%	5.20%		2.50%	2.50%
POL 3	1	0.9	0.03 SD	0.03 SD	0.9	0.00 SD	0.00 SD
			3.50%	3.50%		0.00%	0.00%
In-House	2	5.0	0.05 SD	0.07 SD	4.9	0.07 SD	0.09 SD
			1.00%	1.30%		1.50%	1.90%
POL 1	2	4.9	0.09 SD	0.10 SD	4.8	0.05 SD	0.05 SD
			1.80%	2.10%		1.00%	1.00%
POL 2	2	4.8	0.07 SD	0.12 SD	4.8	0.07 SD	0.08 SD
			1.50%	2.50%		1.50%	1.70%
POL 3	2	4.7	0.10 SD	0.11 SD	4.9	0.10 SD	0.10 SD
			2.10%	2.40%		2.00%	2.00%
In-House	3	8.0	0.18 SD	0.18 SD	7.8	0.20 SD	0.20 SD
			2.30%	2.30%		2.60%	2.60%
POL 1	3	7.9	0.16 SD	0.17 SD	7.9	0.06 SD	0.07 SD
			2.00%	2.20%		0.80%	0.90%
POL 2	3	7.7	0.10 SD	0.16 SD	7.8	0.04 SD	0.10 SD
			1.30%	2.00%		0.60%	1.30%
POL 3	3	7.7	0.09 SD	0.12 SD	8.0	0.08 SD	0.08 SD
			1.20%	1.50%		1.00%	1.10%

Performance Data at POL:

Precision - POL

TBILI			ACE Result mg/dL SD, %CV		Mean	ACE Alera Result mg/dL SD, %CV	
Lab	Sample	Mean	Within-Run	Total		Within-Run	Total
In-House	1	1.2	0.04 SD	0.04 SD	1.2	0.05 SD	0.05 SD
			3.40%	3.70%		4.20%	4.50%
POL 1	1	1.2	0.07 SD	0.07 SD	1.2	0.04 SD	0.04 SD
			5.50%	5.80%		3.20%	3.70%
POL 2	1	1.1	0.05 SD	0.07 SD	1.2	0.06 SD	0.06 SD
			4.00%	6.40%		4.90%	5.00%
POL 3	1	1.1	0.04 SD	0.05 SD	1.1	0.05 SD	0.06 SD
			3.40%	4.40%		4.80%	5.20%
In-House	2	11.5	0.20 SD	0.20 SD	11.3	0.23 SD	0.24 SD
			1.70%	1.80%		2.00%	2.10%
POL 1	2	11.2	0.05 SD	0.42 SD	11.4	0.07 SD	0.09 SD
			0.50%	3.70%		0.70%	0.80%
POL 2	2	11.3	0.05 SD	0.15 SD	11.3	0.17 SD	0.17 SD
			0.50%	1.30%		1.50%	1.50%
POL 3	2	10.9	0.09 SD	0.11 SD	11.2	0.09 SD	0.09 SD
			0.80%	1.00%		0.80%	0.80%
In-House	3	20.9	0.24 SD	0.27 SD	20.6	0.27 SD	0.35 SD
			1.10%	1.30%		1.30%	1.70%
POL 1	3	20.0	0.24 SD	0.24 SD	20.7	0.11 SD	0.12 SD
			1.20%	1.20%		0.50%	0.60%
POL 2	3	20.3	0.21 SD	0.42 SD	20.5	0.11 SD	0.15 SD
			1.00%	2.10%		0.50%	0.70%
POL 3	3	19.9	0.24 SD	0.26 SD	20.3	0.28 SD	0.28 SD
			1.20%	1.30%		1.40%	1.40%

MG			ACE Result mg/dL SD, %CV		Mean	ACE Alera Result mg/dL SD, %CV	
Lab	Sample	Mean	Within-Run	Total		Within-Run	Total
In-House	1	1.7	0.05 SD	0.09 SD	1.7	0.05 SD	0.07 SD
			3.30%	5.70%		3.00%	4.50%
POL 1	1	1.7	0.05 SD	0.11 SD	1.7	0.07 SD	0.10 SD
			3.30%	6.30%		4.20%	5.90%
POL 2	1	1.8	0.08 SD	0.09 SD	1.5	0.09 SD	0.13 SD
			4.60%	5.00%		6.00%	8.40%
POL 3	1	1.7	0.05 SD	0.06 SD	1.7	0.07 SD	0.11 SD
			3.00%	3.50%		3.90%	6.50%

Performance Data at POL: Precision - POL	In-House	2	3.7	0.09 SD 2.50%	0.12 SD 3.30%	3.6	0.07 SD 2.00%	0.09 SD 2.50%
	POL 1	2	3.7	0.05 SD 1.30%	0.11 SD 3.00%	3.8	0.11 SD 2.80%	0.13 SD 3.60%
	POL 2	2	3.7	0.07 SD 1.90%	0.13 SD 3.50%	3.5	0.10 SD 2.90%	0.18 SD 5.20%
	POL 3	2	3.6	0.09 SD 2.50%	0.10 SD 2.80%	3.7	0.08 SD 2.10%	0.13 SD 3.60%
	In-House	3	5.6	0.10 SD 1.80%	0.14 SD 2.60%	5.5	0.05 SD 1.00%	0.10 SD 1.80%
	POL 1	3	5.7	0.09 SD 1.60%	0.11 SD 1.90%	5.8	0.08 SD 1.40%	0.12 SD 2.10%
	POL 2	3	5.6	0.09 SD 1.60%	0.17 SD 3.10%	5.4	0.10 SD 1.90%	0.26 SD 4.80%
	POL 3	3	5.5	0.06 SD 1.10%	0.08 SD 1.40%	5.5	0.05 SD 0.90%	0.09 SD 1.60%

Performance Data:

Method Comparison - POL on ACE

POL – Method Comparison for ACE Clinical Chemistry System

Reagent	Statistic	In-House ACE (x) vs. POL 1 ACE (y)	In-House ACE (x) vs. POL 2 ACE (y)	In-House ACE (x) vs. POL 3 ACE (y)
CO2-LC	n	46	45	45
	Range	3.6 to 42.5	3.6 to 46.2	3.6 to 46.2
	Regression	y = 0.963x – 0.71	y = 0.976x + 1.29	y = 0.984x + 0.42
	Correlation	0.9710	0.9530	0.9908
	Std. Error Est.	1.38	2.10	0.94
	CI Slope	0.893 to 1.034	0.884 to 1.069	0.943 to 1.025
	CI Intercept	-2.34 to 0.92	-0.91 to 3.49	-0.56 to 1.40
Direct Bilirubin	n	49	49	49
	Range	0.1 to 12.4	0.1 to 12.4	0.1 to 12.4
	Regression	y = 1.022x + 0.04	y = 1.003x + 0.11	y = 1.012x + 0.06
	Correlation	0.9986	0.9985	0.9984
	Std. Error Est.	0.14	0.14	0.14
	CI Slope	1.006 to 1.038	0.987 to 1.019	0.995 to 1.029
	CI Intercept	0.00 to 0.08	0.07 to 0.15	0.02 to 0.11
Total Bilirubin	n	48	50	49
	Range	0.2 to 39.3	0.2 to 39.3	0.2 to 39.3
	Regression	y = 0.979x + 0.00	y = 1.000x + 0.04	y = 1.000x + 0.01
	Correlation	0.9995	0.9998	0.9998
	Std. Error Est.	0.27	0.18	0.17
	CI Slope	0.970 to 0.989	0.994 to 1.006	0.994 to 1.006
	CI Intercept	-0.08 to 0.08	-0.01 to 0.09	-0.05 to 0.06
Magnesium	n	51	52	51
	Range	0.6 to 6.1	0.6 to 6.1	0.6 to 6.1
	Regression	y = 0.970x + 0.12	y = 0.975x + 0.16	y = 1.026x – 0.04
	Correlation	0.9902	0.9927	0.9925
	Std. Error Est.	0.13	0.11	0.12
	CI Slope	0.931 to 1.009	0.941 to 1.008	0.989 to 1.062
	CI Intercept	0.03 to 0.21	0.08 to 0.23	-0.13 to 0.04

Performance Data at POL:

Method Comparison - POL on ACE *Alera*

POL – Method Comparison (performed at POC sites) for ACE *Alera* Clinical Chemistry System against the predicate device tested in-house

Reagent	Statistic	In-House ACE (x) vs. POL 1 Alera (y)	In-House ACE (x) vs. POL 2 Alera (y)	In-House ACE (x) vs. POL 3 Alera (y)
CO2-LC	n	45	45	46
	Range	2.0 to 46.0	2.0 to 46.0	2.0 to 46.0
	Regression	y = 0.984x + 0.15	y = 0.972x + 0.57	y = 0.987x + 0.10
	Correlation	0.9903	0.9767	0.9790
	Std. Error Est.	0.95	1.45	1.38
	CI Slope	0.941 to 1.026	0.908 to 1.037	0.926 to 1.049
	CI Intercept	-0.81 to 1.12	-0.90 to 2.05	-1.30 to 1.50
Direct Bilirubin	n	51	51	51
	Range	0.1 to 12.4	0.1 to 12.4	0.1 to 12.4
	Regression	y = 0.995x + 0.09	y = 0.969x + 0.11	y = 0.991x + 0.10
	Correlation	0.9991	0.9984	0.9990
	Std. Error Est.	0.10	0.14	0.11
	CI Slope	0.983 to 1.007	0.953 to 0.985	0.979 to 1.004
	CI Intercept	0.05 to 0.12	0.07 to 0.15	0.06 to 0.13
Total Bilirubin	n	50	50	50
	Range	0.2 to 39.4	0.2 to 39.4	0.2 to 39.4
	Regression	y = 1.020x + 0.02	y = 0.957x + 0.07	y = 0.981x + 0.01
	Correlation	0.9998	0.9991	0.9998
	Std. Error Est.	0.18	0.34	0.16
	CI Slope	1.013 to 1.026	0.945 to 0.968	0.976 to 0.987
	CI Intercept	-0.03 to 0.08	-0.03 to 0.17	-0.04 to 0.06
Magnesium	n	50	50	50
	Range	0.7 to 5.9	0.7 to 5.9	0.7 to 5.9
	Regression	y = 1.010x + 0.00	y = 1.004x – 0.11	y = 0.990x – 0.07
	Correlation	0.9870	0.9886	0.9930
	Std. Error Est.	0.12	0.11	0.09
	CI Slope	0.963 to 1.057	0.960 to 1.048	0.956 to 1.024
	CI Intercept	-0.10 to 0.10	-0.20 to -0.02	-0.14 to 0.00

Performance Data:

ACE *Alera*

Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE *Alera* Clinical Chemistry Systems

Detection Limits - ACE *Alera* Clinical Chemistry System

ACE *Alera*	CO2 (mEq/L)	DBILI (mg/dL)	TBILI (mg/dL)	MG (mg/dL)
LoB	1.27	0.06	0.11	0.26
LoD	1.97	0.08	0.14	0.37
LoQ	3.03	0.12	0.14	0.37

Linearity - ACE *Alera* Clinical Chemistry System

ACE Reagents	Low level tested	Upper level tested	Linear to:	Linear Regression Equation
CO2 (mEq/L)	0.1	53.0	50	y=1.006x + 0.01
DBILI (mg/dL)	0.1	16.0	14.0	y=1.015x + 0.16
TBILI (mg/dL)	0.1	41.6	40.0	y=1.004x + 0.03
MG (mg/dL)	0.4	6.4	6.1	y=0.959x + 0.27

Performance Data:

ACE *Alera*

Interferences - ACE *Alera* Clinical Chemistry System

ACE Alera	Icterus	Hemolysis	Lipemia (Intralipid)/ Triglycerides	Ascorbic Acid
CO2	No significant interference at or below 58.8 mg/dL	No significant interference at or below 250 mg/dL	No significant interference at or below 2388 mg/dL Triglycerides	No significant interference at or below 6 mg/dL
DBili	Not Applicable	No significant interference at or below 62.5 mg/dL	No significant interference at or below 782 mg/dL Triglycerides	No significant interference at or below 6 mg/dL
TBili	Not Applicable	No significant interference at or below 62.5 mg/dL	No significant interference at or below 951 mg/dL Triglycerides	No significant interference at or below 6 mg/dL
MG	No significant interference at or below 50 mg/dL	No significant interference at or below 500 mg/dL	No significant interference at or below 620 mg/dL Triglycerides	No significant interference at or below 6 mg/dL

Performance Data:

ACE *Alera*

Precision - ACE *Alera* Clinical Chemistry System

on ACE *Alera*		*Precision (SD, %CV)*		
		Mean	**Within-Run**	**Total**
CO2 mEq/L	Low	12.8	0.55, 4.3%	1.20, 9.4%
	Mid	15.2	0.48, 3.2%	1.49, 9.8%
	High	21.7	0.82, 3.8%	2.58, 11.9%
DBILI mg/dL	Low	0.3	0.02, 5.3%	0.02, 6.5%
	Mid	1.7	0.04, 2.6%	0.11, 6.6%
	High	3.2	0.08, 2.7%	0.18, 5.6%
TBILI mg/dL	Low	0.5	0.03, 5.7%	0.04, 8.5%
	Mid	3.1	0.04, 1.2%	0.13, 4.1%
	High	7.7	0.08, 1.1%	0.28, 3.7%
MG mg/dL	Low	1.6	0.07, 4.3%	0.08, 5.1%
	Mid	2.5	0.07, 2.6%	0.09, 3.7%
	High	3.6	0.10, 2.7%	0.12, 3.3%

Performance Data:

ACE *Alera*

Method Comparison - ACE *Alera* Clinical Chemistry System

In-House ACE (x) vs. In-House ACE *Alera* (y)

	CO2 (mEq/L)	DBILI (mg/dL)	TBILI (mg/dL)	MG (mg/dL)
n	46	49	49	50
Range	3.6 to 46.2	0.1 to 12.4	0.2 to 39.3	0.6 to 6.1
Slope	0.981	0.998	1.001	0.960
Intercept	-0.6	0.00	0.00	0.12
Correlation Coefficient	0.9974	0.9999	1.000	0.9906
Std. Error	1.45	0.04	0.06	0.10
CI Slope	0.918 to 1.045	0.993 to 1.003	0.999 to 1.003	0.922 to 0.998
CI Intercept	-2.12 to 0.91	-0.01 to 0.01	-0.02 to 0.02	0.04 to 0.21

Conclusions:

Based on the foregoing data, the device is safe and effective for use in clinical laboratories and physician office laboratories. These data indicate substantial equivalence for lithium heparin plasma sample collection tubes to the predicate device's use of serum sample collection tubes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 2, 2013

Alfa Wasserman Diagnostic Technologies, LLC
C/O Hyman Katz, Ph.D.
4 Henderson Drive
WEST CALDWELL NJ 07006

Re: K123953
Trade/Device Name: ACE Carbon Dioxide (CO2-LC) Reagent
ACE Direct Bilirubin Reagent
ACE Total Bilirubin Reagent
ACE Magnesium Reagent
Regulation Number: 21 CFR 862.1160
Regulation Name: Bicarbonate/carbon dioxide test system
Regulatory Class: II
Product Code: KHS, CIG, JGJ
Dated: March 22, 2013
Received: March 25, 2013

Dear Dr. Katz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k123953

Device Name: ACE Carbon Dioxide (CO_2-LC) Reagent

Indications for Use: The ACE Carbon Dioxide (CO2-LC) Reagent is intended for the quantitative determination of carbon dioxide concentration **in serum and lithium heparin plasma** using the ACE, ACE *Alera*, and ACE Axcel Clinical Chemistry Systems. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Device Name: ACE Direct Bilirubin Reagent

Indications for Use: The ACE Direct Bilirubin Reagent is intended for the quantitative determination of direct bilirubin concentration **in serum and lithium heparin plasma** using the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems. Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic, hematological and metabolic disorders, including hepatitis and gall bladder block. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only

Prescription Use X (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices or Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Devices or Radiological Health
510(k) k123953

Indications for Use

510(k) Number (if known): k123953

Device Name: ACE Total Bilirubin Reagent

Indications for Use: The ACE Total Bilirubin Reagent is intended for the quantitative determination of total bilirubin concentration in **serum and lithium heparin plasma** using the ACE, ACE Alera and ACE Axcel Clinical Chemistry System. Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic, hematological and metabolic disorders, including hepatitis and gall bladder block. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Device Name: ACE Magnesium Reagent

Indications for Use: The ACE Magnesium Reagent is intended for the quantitative determination of magnesium in **serum and lithium heparin plasma** using the ACE, ACE Alera and ACE Axcel Clinical Chemistry Systems. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium). This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use X (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices or Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Devices or Radiological Health
510(k) k123953